

REMARKS

Responsive to the Office Action mailed May 16, 2002, with an extension of time of THREE MONTHS, the present Amendment and Reply is timely filed on or before November, 16, 2002. By the present Amendment and Reply, no claims are cancelled, claims 3, 5, 7, and 12 are amended, and new claims 17, 18, and 19 are added. Accordingly, claims 1-19 are in the Application. Entry of the amendments and reconsideration of the Application are respectfully requested.

The Claim Amendments

Claims 3 and 5 are amended to delete express reference to "form V". Support for the amendment can be found in the specification at, for example, page 5 line 9. Claim 3 is also amended to include the experimental error in the x-ray determination. Support for the amendment can be found in the specification at, for example, page 5 lines 13-15.

Claims 7 and 12 are amended to make them multiply dependent from claims 3 and 5. Because the skilled artisan recognizes that the instant invention is drawn to a novel crystalline form of atorvastatin and hydrates thereof, Applicants respectfully submit that support for the amendments can be found in the specification at, for example, page 7 line 5 through page 10, line 18, and in the claims as filed.

A marked-up copy of the claims showing the claim amendments is attached at Tab A.

Applicants respectfully submit that the amendments introduce no new matter.

Rejection Under 35 U.S.C. § 112, Paragraph Second

Claims 1-6 and 16 were rejected under 35 U.S.C. § 112, ¶2 as allegedly being indefinite because two of the claims contain a reference to a figure and, as far as Applicants understand the rejection, the claims are alleged to be of identical scope. Applicants respectfully submit that, when read in light of the entire disclosure, the claims adequately inform the skilled artisan of the meets and bounds of Applicants' invention. Accordingly, Applicants respectfully traverse.

The Office Action alleges that the reference to a figure in claims 1 and 4 is improper and renders the claims "indefinite". Applicants respectfully submit that reference to a figure in a claim comports with 35 U.S.C. § 112 ¶2 in exceptional circumstances when, as here, there is no other practical way of describing *all* of the claim limitations and when

incorporation of the figure itself would be quite cumbersome and would detract from the conciseness of the claim. See M.P.E.P. § 2173.05(g).

Claim 2 refers to the X-ray powder diffraction diagram of FIG. 1 and claim 4 refers to the ^{13}C NMR spectrum of FIG. 2. Applicants respectfully submit that there is no feasible way to introduce - in words or in numbers - *all* of the limitations of the respective instrumental measurements. The means of obtaining the data are described in the specifications in sufficient detail so that the skilled artisan would be able to repeat the measurements, without undue experimentation, and determine if they were in possession of atorvastatin calcium form V that met the limitations of the claims. Accordingly, Applicants respectfully submit that the rejection of claims 2 and 4 on the ground of alleged improper reference to a figure should be withdrawn.

Claims 1-6 were rejected under 35 U.S.C. § 112 ¶2 on the grounds, as Applicants best understand it, that the claims all refer to the same invention (product). Even *if* this statement *were* true, Applicants respectfully submit that it would not render the claims *ipso jure* indefinite.

An inventor is entitled to one patent for one invention. See, e.g. 36 U.S.C. § 101. See also M.P.E.P. § 804 (discussion of double patenting). Each claim of a patent is a separate statement of the invention. See, e.g., *Pall Corp. v. Micron Separations, Inc.*, 36 U.S.P.Q.2d 1225 (Fed. Cir. 1995). Applicants respectfully submit that there is thus nothing inherently improper when an inventor chooses to express his invention using somewhat different words in different statements of the invention (claims) and, as here, the claims are substantially different.

Applicants respectfully submit that it is entirely proper to describe a composition of matter in terms of its characteristics. See M.P.E.P. § 2173.05(t). In claims 2 and 3, Applicants have chosen to describe their novel composition in terms of X-ray diffraction characteristics. Although both claims recite X-ray characteristics, Applicants respectfully submit that the difference in scope of the claims is apparent. In claims 4 and 5 Applicants have chosen to describe their novel composition in terms of ^{13}C NMR characteristics. Although both claims recite ^{13}C NMR data, Applicants respectfully submit that the difference in scope of the claims is apparent.

The Office Action posits that the diffraction patterns are not of hydrates and that the patterns would not be defined by a hydrate. Applicants respectfully submit that this is

contrary to fact. The x-ray diffraction pattern of form V is insensitive to the state of hydration. The skilled artisan would be well aware when they were in possession of anhydrate or a hydrate using well-known routine procedures such as Karl-Fisher or thermogravimetric analysis. Because, Applicants respectfully submit, it is entirely permissible to claim a product in terms of individual characteristics and because the skilled artisan would be reasonably aware of the meets and bounds of the claims, Applicants respectfully submit that the rejection should be withdrawn.

Claim 16 depends from claim 1 and is limited to a pharmaceutical composition having the novel form of atorvastatin calcium, or a hydrate thereof. Applicants respectfully submit that claim 16 introduces a further limitation - contained in a pharmaceutical composition - to the claim from which it depends and is therefore entirely proper and not indefinite. *See* M.P.E.P. § 37 C.F.R. §1.75(c). Accordingly, Applicants respectfully submit that the rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 7-11 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Example 3 of Briggs et al., United States Patent 5,969,156 (the '156 patent). Because the Example 3 of the '156 patent does not provide an enabling disclosure for any method for making atorvastatin calcium form V and, in any event, does not unambiguously describe any method for making any form of atorvastatin calcium that includes either the step of dissolving a metal salt of atorvastatin or the step of isolating atorvastatin form V, Applicants respectfully traverse.

Example 3 of the '156 patent teaches a method of making atorvastatin calcium in form IV starting from atorvastatin lactone in a solvent that includes MTBE and methanol. Example 3 of the '156 patent does not teach the step of dissolving a salt of atorvastatin. Example 3 further teaches contacting a solution of atorvastatin sodium salt with a solution of calcium acetate in water/methanol [15:32], and seeding with atorvastatin calcium form I [15:34]. Example 3 further teaches that a "mixture" is filtered and then slurried [15:37-38]. The nature of the "mixture" is not described and no mention is made of the result or consequence of the filtering process. It is merely speculation that Briggs et al. isolated anything, let alone that they carried out the step of isolating atorvastatin calcium form V as required by Applicants' claims.

In order to anticipate a claim of a patent application, a prior art reference must disclose each and every limitation (element) of the claim, either expressly or inherently. *See* M.P.E.P. § 2131. There is no anticipation by equivalents. *Richardson v. Suzuki Motor Co., Ltd.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989).

Applicants respectfully submit that any allegation that the '156 patent expressly discloses dissolving a salt of atorvastatin or isolating atorvastatin calcium in form V cannot be supported in fact. Whether Briggs et al. obtained a solution of an atorvastatin salt by some means other than that recited in Applicants' claims is, Applicants respectfully submit, irrelevant to anticipation of Applicants' claims.

Inherent disclosure of a claim limitation (element) cannot be established by mere probabilities or possibilities. The mere fact that a given thing may result from a set of circumstances is not sufficient to establish that that thing is inherently disclosed. *In re Robertson*, 49 U.S.P.Q.2d (Fed. Cir. 1999). Example 3 discloses that a "mixture" of what *might* contain atorvastatin calcium was filtered and that the mixture was then slurried [15:37]. It is conjecture that *any* solid, let alone atorvastatin calcium form V, was isolated.

Applicants respectfully submit that the '156 patent does not disclose the steps Applicants' process as recited in claim 7. Accordingly, Applicants respectfully submit that the rejection should be withdrawn. Because the '156 patent does not anticipate Applicants' claim 7, it does not anticipate claims 8-11 that depend from claim 7. Accordingly, Applicants respectfully submit that the rejection of claims 8-11 should be withdrawn.

Claims 12-15 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Example 2 of the '156 patent. Because the '156 patent does not even suggest let alone teach the steps recited in Applicants' claims, Applicants respectfully traverse.

Example 2 of the '156 patent teaches making atorvastatin calcium by *slurrying* atorvastatin calcium in a mixture of methanol and water. Example 2 of the '156 patent does not teach the step of dissolving atorvastatin calcium in a solvent as required by Applicants' claims. Because the '156 patent does not teach all of the elements (limitations) of Applicants' claim 12, or claims 13-15 that depend from it, Applicants respectfully submit that the rejection should be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims are now in condition for allowance, which allowance is earnestly solicited. If,